Reply to Final Office Action of January 26, 2006

Amendments to the Claims:

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-38 (Cancelled)

Claim 39 (Currently Amended) A solid non-effervescent coated compressed dosage form adapted for direct oral administration by swallowing and adapted to disintegrate quickly in the gastro-intestinal tract, comprising a racemic ibuprofen medicament in the form of the sodium salt present to an extent of 35% or more by weight of the dosage form and in homogeneous admixture with a carrier material comprising

i)a. a compressible filler component combined with a disintegrating component; ii)b. 3-20% solid sodium carbonate by weight of the dosage form;

wherein the dosage form is obtained by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa such that said dosage form has a crushing strength in the range 6.5-15 Kp and a disintegration time of less than 10 minutes, and then coating the compressed product, and provided that the ibuprofen medicament does not contain a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

Claim 40 (Previously Presented) A dosage form according to claim 39 comprising a compressible filler component and up to 15% of a discrete disintegrant component by weight of the dosage form.

Claim 41 (Previously Presented) A dosage form according to claim 39 comprising 5-15% sodium carbonate by weight of the dosage form.

Claim 42 (Previously Presented) A dosage form according to claim 39 comprising

Serial Appln. No.: 09/125,114 Response dated April 26, 2006 Reply to Final Office Action of January 26, 2006

sodium carbonate in a weight ratio to the racemic ibuprofen medicament of 1:2 to 1:10.

Claim 43 (Previously Presented) A dosage form according to claim 39 wherein the compressible filler component comprises microcrystalline cellulose, lactose, mannitol or mixtures thereof.

Claim 44 (Previously Presented) A dosage form according to claim 39 wherein the disintegrating component comprises croscarmellose sodium, sodium starch glycollate or mixtures thereof.

Claim 45 (Previously Presented) A dosage form according to claim 39 in the form of a compressed tablet.

Claim 46 (Previously Presented) A dosage form according to claim 39 in the form of a compressed tablet comprising 40-60% sodium salt of ibuprofen by weight of the dosage form, 20-50% one or more compressible fillers by weight of the dosage form, up to 10% of a disintegrant component by weight of the dosage form selected from croscarmellose sodium and sodium starch glycolate, 4-16% of sodium carbonate by weight of the dosage form, up to 4% lubricant by weight of the dosage form and up to 2% flow aid by weight of the dosage form.

Claim 47 (Previously Presented) A dosage form according to claim 39 wherein the compressible filler component is selected from one or more of methyl cellulose, hydroxymethyl cellulose, hydroxypropyl cellulose, microcrystalline cellulose, hydroxypropylmethyl cellulose, hydroxymethylpropyl cellulose phthalate, lactose, sucrose, dextrin, sodium chloride, mannitol, sorbitol cyclodextrin, maltodextrin, calcium phosphate and calcium sulphate.

Serial Appln. No.: 09/125,114 Response dated April 26, 2006 Reply to Final Office Action of January 26, 2006

Claims 48-51 (Cancelled)

Claim 52 (Previously Presented) A solid formulation adapted for direct oral administration by swallowing and adapted to disintegrate quickly in the gastro-intestinal tract, said solid formulation having a coating layer and a core comprising a compressed composition comprising a racemic ibuprofen medicament in the form of the sodium salt in homogeneous admixture with a carrier material, the racemic ibuprofen medicament being present to an extent of 35% or more by weight of the composition and the carrier material comprising a compressible filler component combined with a disintegrating component characterized in that the carrier material comprises 3-20% solid sodium carbonate by weight of the dosage form, wherein the compressed composition is obtainable by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPA to provide a layer having a crushing strength in the range of 6.5-15 Kp and a disintegration time of less than 10 minutes.

Claim 53 (Previously Presented) A solid non-effervescent coated compressed dosage form adapted for direct oral administration by swallowing and adapted to disintegrate quickly in the gastro-intestinal tract comprising a racemic ibuprofen medicament in the form of the sodium salt present to an extent of 35% or more by weight of the dosage form and in homogeneous admixture with a carrier material comprising

- a. a compressible filler component combined with a disintegrating component;
- b. 3-20% solid sodium carbonate by weight of the dosage form;

wherein the carrier is present in an amount of 45 to 55% by weight based on the total weight of the dosage form and the dosage form is obtainable by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa such that said dosage form has a crushing strength in the range 6.5-15 Kp and a disintegration time of less than 10 minutes, and then coating the compressed product, and provided that the ibuprofen medicament does not contain a calcium salt of ibuprofen in combination with an alkali metal salt

Serial Appln. No.: 09/125,114 Response dated April 26, 2006 Reply to Final Office Action of January 26, 2006

of ibuprofen.

Claim 54 (Previously Presented) A dosage form according to claim 39, wherein the dosage form is film-coated.

Claim 55 (Previously Presented) A solid formulation according to claim 52, wherein the solid formulation is film-coated.

Claim 56 (Previously Presented) A dosage form according to claim 53, wherein the dosage form is film-coated.

Claim 57 (Currently Amended) A solid non-effervescent compressed dosage form adapted for direct oral administration by swallowing and adapted to disintegrate quickly in the gastro-intestinal tract, comprising a racemic ibuprofen medicament in the form of the sodium salt present to an extent of 35% or more by weight of the dosage form and in homogeneous admixture with a carrier material comprising

<u>tha.</u> a compressible filler component combined with a disintegrating component; <u>ii)b.</u> 3-20% solid sodium carbonate by weight of the dosage form;

wherein the dosage form is obtained by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa such that said dosage form has a crushing strength in the range 6.5-15 Kp and a disintegration time of less than 10 minutes, provided that the ibuprofen medicament does not contain a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

Claim 58 (Previously Presented) A dosage form according to claim 57 comprising a compressible filler component and up to 15% of a discrete disintegrant component by weight of the dosage form.

Serial Appln. No.: 09/125,114

Response dated April 26, 2006

Reply to Final Office Action of January 26, 2006

Claim 59 (Previously Presented) A dosage form according to claim 57 comprising 5-15% sodium carbonate by weight of the dosage form.

Claim 60 (Previously Presented) A dosage form according to claim 57 comprising sodium carbonate in a weight ratio to the racemic ibuprofen medicament of 1:2 to 1:10.

Claim 61 (Previously Presented) A dosage form according to claim 57 wherein the compressible filler component comprises microcrystalline cellulose, lactose, mannitol or mixtures thereof.

Claim 62 (Previously Presented) A dosage form according to claim 57 wherein the disintegrating component comprises croscarmellose sodium, sodium starch glycollate or mixtures thereof.

Claim 63 (Previously Presented) A dosage form according to claim 57 in the form of a compressed tablet.

Claim 64 (Previously Presented) A dosage form according to claim 57 in the form of a compressed tablet comprising 40-60% sodium salt of ibuprofen by weight of the dosage form, 20-50% one or more compressible fillers by weight of the dosage form, up to 10% of a disintegrant component by weight of the dosage form selected from croscarmellose sodium and sodium starch glycolate, 4-16% of sodium carbonate by weight of the dosage form, up to 4% lubricant by weight of the dosage form and up to 2% flow aid by weight of the dosage form.

Claim 65 (Previously Presented) A dosage form according to claim 57 wherein the compressible filler component is selected from one or more of methyl cellulose, hydroxymethyl cellulose, hydroxyethyl cellulose, hydroxyethyl cellulose, microcrystalline cellulose,

Serial Appln. No.: 09/125,114

Response dated April 26, 2006

Reply to Final Office Action of January 26, 2006

hydroxypropylmethyl cellulose, hydroxymethylpropyl cellulose phthalate, lactose, sucrose, dextrin,

sodium chloride, mannitol, sorbitol cyclodextrin, maltodextrin, calcium phosphate and calcium

sulphate.

Claim 66 (Previously Presented) A dosage form according to claim 57, wherein the dosage

form is coated.

Claim 67 (Previously Presented) A dosage form according to claim 57, wherein the dosage

form is film-coated.

Claim 68 (Previously Presented) A solid formulation adapted for direct oral administration

by swallowing and adapted to disintegrate quickly in the gastro-intestinal tract, said solid formulation

having a layer comprising a compressed composition comprising a racemic ibuprofen medicament

in the form of the sodium salt in homogeneous admixture with a carrier material, the racemic

ibuprofen medicament being present to an extent of 35% or more by weight of the composition and

the carrier material comprising a compressible filler component combined with a disintegrating

component characterized in that the carrier material comprises 3-20% solid sodium carbonate by

weight of the dosage form, wherein the compressed composition is obtainable by compressing said

racemic ibuprofen medicament and said carrier material at a compression force above 80 MPA to

provide a layer having a crushing strength in the range of 6.5-15 Kp and a disintegration time of less

than 10 minutes.

Claim 69 (Previously Presented) A formulation according to claim 68, wherein the

formulation is coated.

Claim 70 (Previously Presented) A formulation according to claim 68, wherein the

formulation is film-coated.

Page 7 of 14

Serial Appln. No.: 09/125,114

Response dated April 26, 2006

Reply to Final Office Action of January 26, 2006

Claim 71 (Previously Presented) A solid non-effervescent compressed dosage form adapted for direct oral administration by swallowing and adapted to disintegrate quickly in the gastro-intestinal tract comprising a racemic ibuprofen medicament in the form of the sodium salt present to an extent of 35% or more by weight of the dosage form and in homogeneous admixture with a carrier material comprising

- a. a compressible filler component combined with a disintegrating component;
- b. 3-20% solid sodium carbonate by weight of the dosage form;

wherein the carrier is present in an amount of 45 to 55% by weight based on the total weight of the dosage form and the dosage form is obtainable by compressing said racemic ibuprofen medicament and said carrier material at a compression force above 80 MPa such that said dosage form has a crushing strength in the range 6.5-15 Kp and a disintegration time of less than 10 minutes, provided that the ibuprofen medicament does not contain a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

Claim 72 (Previously Presented) A dosage form according to claim 71, wherein the dosage form is coated.

Claim 73 (Previously Presented) A dosage form according to claim 71, wherein the dosage form is film-coated.